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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,276	01/04/2006	Nuno Miguel Simoes Dos Santos	VA/H-33271A	4311
74479	7590	07/30/2008		
Novartis Animal Health US Inc. 3200 Northline Avenue, Suite 300 Greensboro, NC 27408				
EXAMINER				
CORDERO GARCIA, MARCELA M				
ART UNIT		PAPER NUMBER		
1654				
MAIL DATE		DELIVERY MODE		
07/30/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,276

Applicant(s)

DOS SANTOS ET AL.

ExaminerMARCELA M. CORDERO
GARCIA**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/5/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-61 is/are pending in the application.
- 4a) Of the above claim(s) 32-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 01/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 26-31 in the reply filed on 05 May 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In addition, Applicant elected SEQ ID NO: 2, readable upon claims 26-31 in the reply filed on 05 May 2008. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of the claims

2. Claims 26-61 are pending in the application. Claims 32-61 are withdrawn as not drawn to the elected group/species. Claims 26-31 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes (WO 01/10459, cited in the IDS dated 4 January 2006).

Barnes teach an isolated protein comprising the 55 kDa extracellular protein of *Photobacterium damsela subsp. piscicida*. Barnes discloses a vaccine comprising an extracellular 55 kDa protein of *Photobacterium damsela subsp. piscicida* for the prophylactic and/or therapeutic treatment of fish for infection by the organism *Photobacterium damsela subsp. piscicida* (e.g., page 1, lines 3-8; page 4, line 7 to page 7, line 35; page 16, line 7 to page 17, line 24; Figures 3 and 7). The limitation of claims 29 and 30: "immunogenic" is inherently taught by a vaccine composition, e.g., in claim 10 and page 4, line 7 to page 5, line 22. The limitation of claims 31: "pharmaceutically acceptable carrier" is taught, e.g., claim 13. Applicant's source bacterium for the isolated protein is *Photobacterium damsela subsp. piscicida* and Barnes' prior art reference also teaches that the isolated protein is from *Photobacterium damsela subsp. piscicida*. Applicant is claiming an isolated protein comprising the extracellular protein of said bacterium, the prior art reference (Barnes) also teaches isolated protein comprising the extracellular protein of said bacterium. Applicant's protein molecular weight is 55 kDa, Barnes' protein molecular weight is also 55 kDa. Therefore, the structure of the protein, i.e., SEQ ID NO:2, as in the limitations of claims 27 and 28 [drawn to SEQ ID NO: 2 and to amino acid residues 17 through 513 of SEQ ID NO: 2], is deemed inherent to the prior art composition which is obtained from the same species (*Photobacterium damsela subsp. piscicida*), the same region within such species (extracellular) and has the same molecular weight (55 kDa) as the claimed composition. It is noted that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' SEQ ID NO: 2 (within the

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claimed 55 kDa extracellular protein of *Photobacterium damsela* subsp. *piscicida* composition) differs and, if so, to what extent, from that of the discussed reference (Barnes). Therefore, the reference is deemed to anticipate the instant claims above, and the burden of establishing non-anticipation by objective evidence is shifted to the Applicants.

Conclusion

7. No claim is allowed. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marcela M Cordero Garcia/
Patent Examiner, Art Unit 1654

MMCG 07/08